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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,099	11/02/2005	Celine Escoffier	279532US0PCT	9427

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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	**PAPER NUMBER**
1651	

NOTIFICATION DATE	DELIVERY MODE
11/27/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/555,099	ESCOFFIER ET AL.	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 17, 2009, has been entered.

Claims 13-26 are cancelled. Claims 1-12 and 27 are pending and examined on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7, 12, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Thorp et al. (US 5,871,918).

Thorp et al. discloses a microelectronic device comprising a microelectronic substrate having first and second faces where the conductive electrode is on the first face, and an oligonucleotide capture probe is immobilized on the first face adjacent to the conductive electrode (column 21, lines 20-27). The capture probe is spaced close to the adjacent probe, from about 0.1 to 1000 μ (column 21, lines 27-30). Thus, there is an attachment zone functionalized with a probe (an oligonucleotide) where there is an empty space separating the

attachment zone with the electrode. Given that the probe is an oligonucleotide listed as a probe in instant claim 12, the oligonucleotide probe is capable of binding, according to pH, to a target so as to attach it, thus meeting the limitation of instant claim 7. Moreover the attachment zone is in the form of an electrode since an electrode can be in any form (variety of sizes and shapes).

Figures 9 and 10 show an embodiment of the invention where separate oligonucleotide capture probes are immobilized adjacent to electrodes (column 21, lines 33-37). Given that there are multiple electrodes, each of the electrodes may be a working electrode, a counterelectrode, or a reference electrode. Furthermore, any one of the electrodes is surrounded by other electrodes as shown in the figures. Thus there is at least one counterelectrode that surrounds a working electrode, thus meeting the limitations in instant claim 2. From Figures 9 and 10, it is clear that the attachment zone and the working electrode are coplanar. Moreover, each electrode is electrically connected to a contact 23 so that the device may be wired with the necessary electronic equipment (column 21, lines 41-45). Thus, there is a means for applying a given electric current or a given potential to any of the electrodes (including a working electrode).

Claims 1, 2, 4-7, 12, and 27 are anticipated even though Thorp et al. does not specify that when the attachment zone and the electrodes are immersed in an aqueous solution, a local variation in pH occurs in the region of the attachment zone, or that the reference electrode measures the potential applied to the working electrode. There is anticipation since MPEP 2114 points out that "A claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim."

A holding of anticipation is clearly required.

Claims 1, 2, 4-7, 12, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Choong et al. (US 6,238,909).

Choong et al. teaches a device comprising a substrate, one or a plurality of microlocations on the substrate where each microlocation comprises a binding entity, two or more electrodes adapted to receive charge, and a source for providing charge to the electrode(s) (column 3, lines 37-54). The electrodes are separated from one another and from the microlocations (column 3, lines 55-61). Note that the electrodes can be in contact with the substrate (column 8, lines 42-45), where the electrodes can be placed directly on a surface of the substrate (column 9, lines 38-40). Clearly Choong et al. teaches a support (the substrate) comprising an attachment zone functionalized with a probe (the microlocations each comprising binding entities) and wherein electrodes are on the support (the substrate) bordering or surrounding the attachment zone (microlocations). Thus, the attachment zone (microlocations) and the electrodes are coplanar, as required by instant claim 27. The source for providing the charge to the electrodes of the Choong invention is considered a means for applying a given electric current or a given potential to the electrode(s). Further still, there is clearly an empty space separating the attachment zone and the electrodes since Choong requires that the electrodes are separated from the microlocations.

Given that there are multiple electrodes, each of the electrodes may be a working electrode, a counterelectrode, or a reference electrode. The electrodes can be configured as three electrodes forming a triangle in one plane (column 9, lines 62-63), thus there is a counterelectrode bordering or surrounding a working electrode, as required by instant claim 2. Also, the attachment zone is in the form of an electrode since an electrode can be in any form

(variety of sizes and shapes). The binding entity present in the microlocations (attachment zone) can be an oligonucleotide, a protein, or an antibody (column 4, lines 21-30), thus meeting limitations in instant claim 12. The binding entity can comprise a probe where a hybridization reaction occurs to bind the probe with target nucleic acid under hybridizing conditions, such as a suitable pH (column 14, lines 3-13). Thus, the limitations in instant claim 7 are taught by Choong et al.

Claims 1, 2, 4-7, 12, and 27 are anticipated even though Choong et al. does not specify that when the attachment zone and the electrodes are immersed in an aqueous solution, a local variation in pH occurs in the region of the attachment zone, or that the reference electrode measures the potential applied to the working electrode. There is anticipation since MPEP 2114 points out that "A claim containing a 'recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus' if the prior art apparatus teaches all the structural limitations of the claim."

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choong et al. in view of Segev (US 5,843,650).

As discussed above, Choong et al. anticipates claims 1, 2, 4-7, 12, and 27. However, Choong et al. does not expressly disclose that the binding entities are capable of binding to targets so as to attach them by an electrophilic or nucleophilic group, such as an activated ester, or an amine, or that the binding entities are chosen so that they can form with the target molecules a peptide bond.

Segev discloses a method and kit for detecting a target nucleic acid sequence which may be present in a test sample (column 5, lines 48-50). A pair of oligonucleotide probes is used, wherein one member of the pair has a nucleophilic chemical functionality group and the other pair has an electrophilic chemical functionality group (column 23, lines 46-50). The target molecule bonds with the oligonucleotide probes by chemical functionality groups (column 26, lines 20-24).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used the oligonucleotide probes of Segev as the oligonucleotides binding entities of the Choong invention. One of ordinary skill in the art would have been motivated to

do this since the Segev oligonucleotide probes are suitable for binding with nucleic acids. Therefore, there is attachment by an electrophilic or nucleophilic group to the target nucleic acid. It would have been obvious to have used activated ester or amine as the chemical functionality group of the one or more molecules on the substrate as they are known electrophilic/nucleophilic groups. Moreover, because of the different chemical funcitionality groups that may be used as oligonucleotide probes, it would have been obvious that different bonds, including peptide bonds, would have formed between the target molecules and the oligonucleotide probes used as the binding entity of the Choong invention. Thus, claims 8-11 are rendered obvious.

Furthermore, Choong et al. does not expressly disclose that any two electrodes (a working electrode and a counterelectrode) and the microlocation (attachment zone) are in a design selected from the group consisting of an interdigitated comb design, a spiral design, and a concentric design. However, the arrangement of the electrodes relative to the attachment zone of the Choong invention would have been a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular arrangement was significant. Moreover, Choong et al. indicates that "the electrodes can be positioned vis-à-vis the other electrodes, and vis-à-vis the substrate, in any conceivable fashion in which the devices of the invention can be constructed, and in which the methods of the invention can be carried out" (column 9, lines 34-38). Therefore, claim 3 is rendered obvious.

A holding of obviousness is clearly required.

Claims 1, 2, 4-12 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorp et al. in view of Segev (US 5,843,650).

As discussed above, Thorp et al. anticipates claims 1, 2, 4-7, 12, and 27. However, Thorp et al. does not expressly disclose that the oligonucleotide capture probe is capable of binding to targets so as to attach them by an electrophilic or nucleophilic group, such as an activated ester, or an amine, or that the capture probe is chosen such that they can form with the target molecules a peptide bond.

Segev discloses a method and kit for detecting a target nucleic acid sequence which may be present in a test sample (column 5, lines 48-50). A pair of oligonucleotide probes is used, wherein one member of the pair has a nucleophilic chemical functionality group and the other pair has an electrophilic chemical functionality group (column 23, lines 46-50). The target molecule bonds with the oligonucleotide probes by chemical functionality groups (column 26, lines 20-24).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used the oligonucleotide probes of Segev as the oligonucleotides capture probes of the Thorp invention. One of ordinary skill in the art would have been motivated to do this since the Segev oligonucleotide probes are suitable for binding with nucleic acids. Therefore, there is attachment by an electrophilic or nucleophilic group to the target nucleic acid. It would have been obvious to have used activated ester or amine as the chemical functionality group of the one or more molecules on the substrate as they are known electrophilic/nucleophilic groups. Moreover, because of the different chemical funcitionality groups that may be used as oligonucleotide probes, it would have been obvious that different bonds, including peptide bonds, would have formed between the target molecules and the oligonucleotide probes used as the binding entity of the Thorp invention. Thus, claims 8-11 are rendered obvious.

Note that it would have been obvious to have substituted the oligonucleotide probe with other probes including those listed in instant claim 12 since these probes are suitable for binding to products, thus enabling the use of the apparatus for other assays.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments with respect to the rejection(s) of claim(s) 1-12 and 27 under Montgomery and Ackley have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Choong et al. and Thorp et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef